November 17, 2022

Siemens Medical Solutions
% Denise Adams
Regulatory Affairs Professional
40 Liberty Boulevard
MALVERN PA 19355

Re: K221281
Trade/Device Name: Multitom Rax
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA, JAK
Dated: October 18, 2022
Received: October 19, 2022

Dear Denise Adams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221281

Device Name
Multitom Rax

Indications for Use *(Describe)*
Multitom Rax is a device intended to visualize anatomical structures by converting an X- ray pattern into a visible image. The system has medical applications ranging from gastrointestinal examinations to cranial, skeletal, thoracic and lung exposures as well as examinations of the urogenital tract. The unit may also be used in emergency applications, lymphography, endoscopy, myelography, venography, arthrography, interventional radiology, digital angiography, and digital subtraction angiography (DSA). The system may be used on pediatric, adult, and bariatric patients.

The True2scale Body Scan functionality (i.e., slot-scanning-based acquisition and reconstruction technique) of the Multitom Rax is intended to be used for the generation of a geometrically accurate (in scanning direction) 2-D representation of the spine, the lower limbs or the full body which may be used for the assessment of body axes and skeletal alignment. The True2scale Body Scan is not intended to be used for interventional purposes.

The Real3D functionality (i.e., cone-beam CT acquisition and reconstruction technique) of the Multitom Rax is intended to be used for 3-D bone imaging of the head, the upper and lower extremities as well as the lumbar spine. Real3D is not intended for imaging of the torso of patients with a Body Mass Index (BMI) exceeding 30 kg/m².

Multitom Rax is not for mammography examinations.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary: Multitom Rax

Company: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355

Date Prepared: November 16, 2022

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA of 1990 and 21 CFR § 807.92.

1. General Information:

Importer / Distributor:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Establishment Registration Number: 2240869

Location of Manufacturing Site:
Siemens Healthcare GmbH
Siemensstr. 1
91301 Forchheim, Germany
Establishment Registration Number: 3004977335

2. Contact Person:

Denise Adams,
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Alternate Contact Person:
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Senior Regulatory Affairs Manager
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3. Device Name and Classification:

Trade Name: Multitom Rax

Classification Name: Image-intensified fluoroscopic x-ray system
Classification Panel: Radiology
Classification Regulation: 21 CFR §892.1650
Device Class: II
Product Code: OWB
Secondary Product Code: JAA, JAK

4. Legally Marketed Predicate Device:

Trade Name	**Multitom Rax With True2scale Body Scan Option**
Company	Siemens Medical Solutions USA, Inc.
510(k) Number	K212212
Device Classi-ficationName	Interventional Fluoroscopic X-ray System
Regulation Number	892.1650
Review Panel	Radiology
Product Code	OWB
Secondary Product Code	JAA
Device Class	2

5. Legally Marketed Reference Device:

Trade Name	**LineUP**
Company	CurveBeam, LLC
510(k) Number	K180727
Device Classi-ficationName	Computed tomography X-ray System
Regulation Number	892.1750
Review Panel	Radiology
Product Code	JAK
Device Class	2

6. Device Description:

Multitom Rax is a stationary X-ray system for radiography and fluoroscopy. Multitom Rax consists of a floor mounted patient table (option) and ceiling suspended X-ray tube, and a ceiling suspended Solid State X-ray Imager (SSXI). Together with an X-ray generator and a digital imaging system, Multitom Rax provides comprehensive image acquisition modes to support radiographic and fluoroscopic imaging procedures.

With the True2scale Body Scan technology, Multitom Rax performs a continuous scan that moves along the patient's vertical axis with a highly collimated radiation beam along a line trajectory using the system's two telescopic arms. The projections, which are acquired during the scanning process, form the basis for a reconstruction to obtain a 2D representation of the scanned object.

With the Real3D technology, Multitom Rax performs a continuous, circular scan around the patient using the system's two telescopic arms. The projections, which are acquired during the scanning process, form the basis for a reconstruction to obtain a 3D representation of the scanned object.

7. Indication for Use:

Multitom Rax is a device intended to visualize anatomical structures by converting an X-ray pattern into a visible image. The system has medical applications ranging fromgastrointestinal examinations to cranial, skeletal, thoracic and lung exposures as well as examinations of the urogenital tract. The unit may also be used in emergency applications,lymphography, endoscopy, myelography, venography, arthrography, interventional radiology, digital angiography, and digital subtraction angiography (DSA). The system may be used on pediatric, adult, and bariatric patients.

The True2scale Body Scan functionality (i.e., slot-scanning-based acquisition and reconstruction technique) of the Multitom Rax is intended to be used for the generation of a geometrically accurate (in scanning direction) 2-D representation of the spine, the lower limbs or the full body which may be used for the assessment of body axes and skeletal alignment. The True2scale Body Scan is not intended to be used for interventional purposes.

The Real3D functionality (i.e., cone-beam CT acquisition and reconstruction technique) of the Multitom Rax is intended to be used for 3D bone imaging of the head, the upper and lower extremities as well as the lumbar spine.
Real3D is not intended for imaging of the torso of patients with a Body Mass Index (BMI) exceeding 30 kg/m².

Multitom Rax is not for mammography examinations.

8. Substantial Equivalence:

The subject device is the same as the predicate device. The software was updated and new CBCT trajectories have been introduced. The Real3D (CBCT) functionality has been tested and does not raise any new concerns of safety and effectiveness. A comparison to a legally marketed CBCT device was done and supports substantial equivalence.

The device remains within the same classification regulation for the same technology as the predicate device with the addition of computed tomography. The system software design was completed in accordance with Siemens Quality Management System Design Controls. The scope of internationally recognized standards compliance remains the same.

9. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:

The software of the subject device was updated and new CBCT trajectories have been added.

Comparison of the Subject Device (Multitom Rax) to the PredicateDevice (Multitom Rax With True2scale Body Scan Option)

Feature	**Predicate device Multitom Rax With True2scale Body Scan Option**	**Subject device Multitom Rax**	**Comment**
Regulation Description	Image-intensified fluoroscopic X-ray system	Image-intensified fluoroscopic X-ray system	Same
Regulation Number	892.1650	892.1650	Same
Classification Product Code	OWB	OWB	Same
Secondary Product Code	JAA	JAA, JAK	New product code for CBCT
Indications for use	Multitom Rax is a device intended to visualize anatomical structures by converting an X-ray pattern into a visible image. The system has medical applications ranging from gastrointestinal examinationsto cranial, skeletal, thoracic and lung exposures as well asexaminations of the urogenital tract. The unit may also be used in emergency applications, lymphography, endoscopy, myelography, venography, arthrography, interventional radiology, digital angiography, and digital subtraction angiography (DSA). The system may be	Multitom Rax is a device intended to visualize anatomical structures by converting an X-ray pattern into a visible image. The system has medical applications ranging from gastrointestinal examinationsto cranial, skeletal, thoracic and lung exposures as well as examinations of the urogenital tract. The unit mayalso be used in emergency applications, lymphography, endoscopy, myelography, venography, arthrography, interventional radiology, digital angiography, and digital subtraction angiography (DSA). The system may be used on pediatric, adult, and	Real3D added to Indications for Use

	used on pediatric, adult, and bariatric patients. The True2scale Body Scan functionality (i.e., slot-scanning-based acquisition and reconstruction technique) of the Multitom Rax is intended to be used for the generation of a geometrically accurate (in scanning direction) 2-D representation of the spine, the lower limbs or the full body which may be used for the assessment of body axes and skeletal alignment. The True2scale Body Scan is not intended to be used for interventional purposes. Multitom Rax is not for mammography examinations.	bariatric patients. The True2scale Body Scan functionality (i.e., slot-scanning-based acquisition and reconstruction technique) of the Multitom Rax is intended to be used for the generation of a geometrically accurate (in scanning direction) 2-D representation of the spine, the lower limbs or the full body which may be used for the assessment of body axes and skeletal alignment. The True2scale Body Scan is not intended to be used for interventional purposes. The Real3D functionality (i.e., cone-beam CT acquisition and reconstruction technique) of the Multitom Rax is intended to be used for 3D bone imaging of the head, the upper and lower extremities as well as the lumbar spine. Real3D is not intended for imaging of the torso of patients with a Body Mass Index (BMI) exceeding 30 kg/m². Multitom Rax is not for mammography examinations.	
Scan axis	Horizontal and Vertical	Horizontal and Vertical	Same
Mechanical System design	Tube and detector both move on rails with three translational and two rotational degrees of freedom. They can move on defined paths (trajectories) around the patient to acquire the	Tube and detector both move on rails with three translational and two rotational degrees of freedom. They can move on defined paths (trajectories) around the patient to acquire the projections.	Same

	projections.		
High voltage generator	High frequency generator 65 or 80 kW	High frequency generator 65 or 80 kW	Same
X-Ray Tube	Max anode heat capacity 820 kHU (Nominal) Focal size: 0.6 / 1.0	Max anode heat capacity 820 kHU (Nominal) Focal size: 0.6 / 1.0	Same
Image detector	SSXI with Cesium Iodide scintillator	SSXI with Cesium Iodide scintillator	Same
Gray scale	16 bit	16 bit	Same
Patient Support Structure	Floor mounted patient table for supine examinations. Patient support device for standing patient.	Floor mounted patient table for supine examinations. Patient support device for standing patient.	Same
Cone-beam CT functionality	N/A	Trajectories for CBCT image acquisition allowing various Source-to-Imager and Source-to-Isocenter Distances parallel to axis of rotation. The X-ray beam is collimated to a rectangular shape matching the 43 cm x 43 cm flat panel detector (with a narrow unexposed margin). For the high-resolution mode, the beam size is limited to 21 cm x 21 cm.	Added support for CBCT functionality
		Scans available for upper and lower extremities, head, and lumbar spine.	
		Filtered backprojection-based reconstruction for CBCT, which accounts for the acquisition geometry.	
		Metal Artifact Reduction for CBCT	

Comparison of the CBCT-functionality of the Subject Device (Multitom Rax) to the Reference Device (LineUP)

Feature	CurveBeam LineUp	Multitom Rax Real3D	Comment
kVp	100 - 120	60 - 130	Better for Multitom Rax Real3D
Voxel size	0.3 mm	0.2 mm - 0.5 mm (depending on chosen reconstruction kernel)	Better for Multitom Rax Real3D
Slice spacing	0.3 mm	0.2 mm - 0.5 mm (depending on chosen reconstruction kernel	Better for Multitom Rax Real3D
FOV (diameter, height)	Regular: 20 cm x 20 cm (d, h) Extended: 35 cm x 20 cm (d, h)	Real 3D Hi-Res: 15 cm x 15 cm (d, h) Real3D: 23 cm x 23 cm (d, h)	Extended FOV not available at Multitom Rax Regular FOV is bigger for Multitom Rax Real3D
Scan time*	23s or 26s	Real3D Hi-Res: 14s Real3D: 12s or 16s (depending on anatomy)	Better for Multitom Rax Real3D and Real3D Hi-Res *Scan time is defined as the duration in which the exposure alarm (buzzer) is ON and X-ray ON light is illuminated
High-contrast resolution (10% MTF)	12 lp/cm	Real 3D Hi-Res: up to 25 lp/cm (very sharp kernel) Real 3D: up to 15 lp/cm (sharp kernel)	Better for Multitom Rax Real3D
Low-contrast detectability	n/a	20 HU @ 4 mm (smooth kernel) 10 HU @ 8 mm (smooth kernel)	Not reported for CurveBeam LineUp. Also, the intended use of Real3D is high-contrast bone imaging, therefore the low-contrast detectability is not of as high importance as it would be for hemorrhage detection.

Slice Sensitivity Profile / z-axis point spread function	The LineUP has a fixed and rigid patient positioning platform that does not incorporate any table motion or indexing (no "table pitch"). The detector panel has a square shape, while the pixels on the panels are square shaped as well. The raw projections are acquired in a single 360° orbit, thus covering the entire Field of View (FOV) height in one rotation. This results in isotropic voxels in the reconstructed volume, hence the same spatial resolution in the z-axis as in the x-y plane. Due to this projection geometry, calculation of a separate z-axis point spread function should not be applicable.	0.42 mm ± 0.1 mm (Real3D) 0.31 mm ± 0.1 mm (Real 3D Hi-Res)	Not reported for CurveBeam LineUp. Isotropic resolution for Multitom Rax Real3D.
Image noise	n/a	Smooth: 20 ± 15 HU Medium: 60 ± 40 HU Sharp: 100 ± 60 HU Very sharp: 300 ± 150 HU	Not reported for CurveBeam LineUp. Also, as noise depends on both, radiation dose and the imaged object and the used post-processing (reconstruction kernel), a direct comparison of two devices is mostly not feasible.
Uniformity (in-plane)	< 100 HU	< 150 HU	Better for CurveBeam LineUp Justification: Intended use of Real3D is high-contrast bone imaging, therefore the in-plane uniformity should at least allow to apply standard viewing windowing functions (typical bone windows are, for instance, 2000 HU / 300 HU (W/C) or 1500 HU/ 450HU (W/C)), which is fulfilled for the CBCT functionality

			of the Multitom Rax.
CT Number Accuracy	Air: -1000 ± 200 HU Water: 0 ± 150 HU Bone (400 mg CaHA/ccm): n/a	Air: -1000 ± 250 HU Water: 0 ± 150 HU Bone (400 mg CaHA/ccm): 450 ± 150 HU	Air: Better for CurveBeam LineUp Water: equivalent Bone: Not reported for CurveBeam LineUp. Justification: Intended use of Real3D is high-contrast bone imaging, therefore the CT number accuracy should allow to apply standard viewing windowing functions (typical bone windows are, for instance, 2000 HU / 300 HU (W/C) or 1500 HU/ 450HU (W/C)) which is fulfilled for the CBCT functionality of the Multitom Rax.

10. Summary of Non-Clinical Tests:

The Multitom Rax VF11 software design was completed in accordance with Siemens Quality Management System Design Controls and verification and validation testing were successfully conducted. The following performance tests were conducted:

- High-contrast Resolution (MTF)
- Low-contrast Detectability
- CT Number Accuracy
- Uniformity
- Image Noise (in-plane)
- Image Noise (z-direction)
- Slice Sensitivity Profile (SSP)
- Noise Power Spectrum (NPS)
- CTDI measurements/accuracy

The Real3D image output should not be used for quantitative HU-value based diagnoses.

11. Summary of Tests to comply with International Standards

The device complies with the voluntary standards as listed in the following table:

Standards Development Organization and Reference Number	Title of Standard
ANSI AAMI 60601-1, 2012 Ed. 3.1	Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC 60601-1-2 2014 Ed 4.0	Medical Electrical Equipment - Part 1-2: Generalrequirements for basic safety and essential performance -Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests
IEC 60601-1-3: Edition 2.1, 2013	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance -Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-2-28, 2017	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
IEC 60601-2-54 2018, Edition 1.2	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
IEC 60601-1-6 2013 Ed 3.1	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance –Collateral standard: Usability
IEC 62366-1 2015 Ed 1.0	Medical devices – Application of usability engineering to medical devices
ISO 14971: 2019	Medical devices – application of risk management to medical devices
IEC 62304 2015, Ed.1.1	Medical device software - Software life cycle processes
IEC 61910-1: 2014, Ed 1.0	Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reportsfor radiography and radioscopy
NEMA PS 3.1 - 3.20 2016	Digital Imaging and Communications in Medicine (DICOM) Set
IEC 60601-2-43: 2017	Medical electrical equipment - Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures
ISO EN ISO 15223-1 2017-04	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

IEC 62220-1-1:2015	Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1-1: Determination of the detective quantum efficiency –Detectors used in radiographic imaging

12. Summary of Clinical Tests:

For the subject of this premarket submission, Siemens did a Customer Use Test over the course of three months as well as a dedicated evaluation of the image quality.

The purpose of the Customer Use Test was to proof the effectiveness of the changes between VF10 and VF11, focusing on the performance of the Real3D functionality in terms of workflow and image quality. The analysis of the feedback material stated that the MTR Real3D can be used for CBCT bone imaging of hand, wrist, foot, ankle, knee, and lumbar spine and was vastly improved compared to the predecessor version.
In addition, an image quality evaluation of 21 anonymized clinical and phantom data sets including images of the foot, ankle, knee, hip, lumbar spine, elbow, hand, and head by expert US board-certified radiologists was conducted showing that presented 3D images are of sufficient diagnostic quality to assess osseous structures including fractures and bone angles.

13. General Safety and Effectiveness Concerns:

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner. Several safety features including visual and audible warnings are incorporated into the system design. In addition, the device is continually monitored, and if an error occurs, the system functions will be blocked, and an error message will be displayed.

Furthermore, the operators are health care professionals familiar with and responsible for the X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

14. Conclusion as to Substantial Equivalence:

The Multitom Rax that is the subject of this 510(k) is the same as the predicate device. The software was updated and new CBCT trajectories have been introduced, and the Indications for Use have been updated to include language about the Real3D feature. A comparison to a legally marketed CBCT device was done and supports substantial equivalence.
Therefore, Siemens concludes the subject device is substantially equivalent to the predicate and the reference device.

15. Guidance documents

The following FDA guidance documents were utilized in this Premarket Notification:

Provision for Alternate Measure of the Computed Tomography Dose Index (CTDI) to Assure Compliance with the Dose Information Requirements of the Federal Performance Standard for Computed Tomography Document issued on October 20, 2006

Content of Premarket Submission for Management of Cybersecurity in Medical Devices - Guidance for Industry and Food and Drug Administration Staff Document Issued on October 2, 2014

Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices - Guidance for Industry and Food and Drug Administration Staff Document issued on July 11, 2016

Guidance for Industry and FDA Staff - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
Document issued on May 11, 2005

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices - Guidance for Industry and Food and Drug Administration Staff Document issued on September 14, 2018.

The 510(k) Program: Evaluation Substantial Equivalent in Premarket Notifications 510(k) - Guidance for Industry and Food and Drug Administration Staff Document issued on July 28, 2014